

WHAT IS CLAIMED IS:

- Break
- 6,184,210⁵
- Ex 21
- 10
- 15
- 20
- 25
- 30
1. An apparatus for containing a biological sample, comprising:
a container having a reservoir portion for receiving the sample; and
a stabilizing agent in the reservoir of the container, the agent comprising
a caspase inhibitor.
 2. The apparatus of claim 1, wherein the container is selected from the
group consisting of tubes, closed system blood collection devices, collection bags,
syringes, pre-filled syringes, catheters, microtiter plates, multi-well collection devices,
flasks, spinner flasks, roller bottles, vials, pipettes, pipette tips and tissue and other
biological sample collection containers.
 3. The apparatus of claim 1, wherein the container is a tube having a first
end and a second end.
 4. The apparatus of claim 3, further comprising a separating member
disposed in the container.
 5. The apparatus of claim 4, wherein the separating member is a
mechanical separating element.
 6. The apparatus of claim 5, wherein the mechanical separating element is
at least partially coated with the at least one stabilizing agent.
 7. The apparatus of claim 5, wherein the mechanical separating element is
substantially inert with respect to the stabilizing agent.
 8. The apparatus of claim 4, wherein the separating member is a gel.
 9. The apparatus of claim 8, wherein the gel separating member is
physically separated from the stabilizing agent.
 10. The apparatus of claim 1, wherein the stabilizing agent is in a form
selected from the group consisting of a solution, suspension or other liquid, a pellet, a
tablet, a capsule, a spray-dried material, a freeze-dried material, a powder, a particle, a
gel, crystals or a lyophilized material.
 11. The apparatus of claim 10, wherein the stabilizing agent is lyophilized.
 12. The apparatus of claim 1, wherein the caspase inhibitor inhibits one or
more cysteinyl aspartic acid proteases.

13. The apparatus of claim 1, wherein the stabilizing agent comprises more than two caspase inhibitors.
14. The apparatus of claim 1, further comprising a carrier media.
15. The apparatus of claim 1, further comprising a stabilizing media.
- 5 16. The apparatus of claim 15 wherein the stabilizing media is trehalose.
17. The apparatus of claim 1, further comprising at least one antioxidant.
18. The apparatus of claim 1, further comprising at least one reducing agent.
19. The apparatus of claim 1, further comprising at least one buffering agent.
- 10 20. The apparatus of claim 3, further comprising a closure means for sealing the first end.
21. The apparatus of claim 20, wherein the tube is partially evacuated.
22. The apparatus of claim 21, wherein the stabilizing agent is lyophilized.
23. The apparatus of claim 22, wherein the stabilizing agent comprises more than two caspase inhibitors.
- 15 24. The apparatus of claim 23, wherein the tube further comprises an anticoagulant.
25. The apparatus of claim 24, wherein the anticoagulant is spray-dried onto at least a portion of an interior wall.
- 20 26. The apparatus of claim 25, wherein the anticoagulant comprises a salt of EDTA.
27. The apparatus of claim 24, wherein the anticoagulant comprises heparin.
-
28. A tube for collecting and stabilizing a biological sample, comprising:
a first end, a second end and at least one interior wall defining a
25 reservoir portion for receiving the sample;
at least one stabilizing agent in the reservoir of the container, the stabilizing agent comprising a caspase inhibitor;
a thixotropic polymeric gel in the reservoir; and
an element for maintaining separation of the stabilizing agent and the
30 gel.

29. The tube of claim 28, wherein the element for maintaining separation is a capsule.
30. The tube of claim 29, further comprising a closure means for sealing the first end.
- 5 31. The tube of claim 30, wherein the closure means is pierceable by a needle for supplying the sample to the tube.
32. The tube of claim 30, wherein the tube is partially evacuated.
33. The tube of claim 32, wherein the stabilizing agent is lyophilized.
34. The tube of claim 33, wherein the stabilizing agent comprises more than
10 two caspase inhibitors.
35. The tube of claim 33, wherein the tube further comprises an anticoagulant spray-dried onto at least a portion of the interior wall.
-
36. A tube for collecting and stabilizing a biological sample, comprising:
a first end, a second end and at least one interior wall defining a
15 reservoir portion for receiving the sample;
at least one stabilizing agent in the reservoir of the tube the agent comprising a caspase inhibitor; and
a mechanical separating element in the reservoir.
37. The tube of claim 36, wherein the mechanical separating element is
20 substantially inert with respect to the stabilizing agent.
38. The tube of claim 36, further comprising a closure means for sealing the first end.
39. The tube of claim 38, wherein the closure means is pierceable by a needle for supplying the sample to the tube.
- 25 40. The tube of claim 38, wherein the tube is partially evacuated.
41. The tube of claim 40, wherein the stabilizing agent is lyophilized.
42. The tube of claim 41, wherein the stabilizing agent comprises more than two caspase inhibitors.
43. The tube of claim 41, wherein the tube further comprises an
30 anticoagulant spray-dried onto at least a portion of the interior wall.

44. A kit for collecting and storing a biological sample for subsequent testing, comprising:

a primary collection tube having a separator element therein; and
a secondary tube;

5 wherein the primary collection tube and the secondary tube contain one or more stabilizing agents, the agents comprising one or more caspase inhibitors.

45. The kit of claim 44, wherein the separator element is a mechanical separating element.

46. The kit of claim 45, wherein the mechanical separating element is at least partially coated with the one or more stabilizing agents.

47. The kit of claim 46, wherein the mechanical separating element is substantially inert with respect to the one or more stabilizing agents.

48. The kit of claim 44, wherein the separator element is a gel, and the gel is physically separated from the stabilizing agent..

49. The kit of claim 44, further comprising a tube-to-tube transfer device.

50. The kit of claim 49, wherein the second tube is maintained at a pressure to draw the sample from the first tube through the tube-to-tube transfer device and into the second tube.

51. A method of stabilizing a biological sample, comprising:

providing a sample collection container; and

disposing the biological sample into the collection container such that the sample is contacted with a stabilizing agent comprising a caspase inhibitor.

52. The method of claim 51, wherein the sample collection container includes the stabilizing agent before collecting the biological sample.

53. The method of claim 51, wherein the disposing of the biological sample into the container and the contacting of the sample with the stabilizing agent are performed in the same collection container.

54. The method of claim 53, wherein the collection container is evacuated and has a predetermined internal pressure sufficient to draw a predetermined volume of the sample into the collection container.

55. The method of claim 51, wherein the collection container is selected from the group consisting of tubes, closed system blood collection devices, collection bags, syringes, microtiter plates, multi-well collection devices, flasks, spinner flasks, roller bottles and vials.

5 56. The method of claim 51, wherein the stabilizing agent comprises more than two caspase inhibitors.

65
57. The method of claim 51, wherein the biological sample is selected from the group consisting of whole blood or a component thereof, umbilical cord or placental blood, red blood cell concentrates, platelet concentrates, leukocyte concentrates, plasma, serum, urine, bone marrow aspirates, cerebral spinal fluid, tissue, cells, feces, saliva and oral secretions, nasal secretions and lymphatic fluid.

58. The method of claim 57, wherein the biological sample is whole blood.

59. The method of claim 58, wherein the whole blood is collected from a patient directly into the collection container.

15 60. The method of claim 59, wherein the collection container includes the stabilizing agent before the blood is collected from the patient.

61. A method for making a collection container for collecting a biological sample, comprising:

providing a collection container;

20 disposing a stabilizing agent comprising at least one caspase inhibitor into the container;

lyophilizing the stabilizing agent;

evacuating and sealing the container; and

sterilizing the container.

25 62. The method of claim 61, wherein the collection container is a tube.

63. The method of claim 62, further comprising placing into the tube a separating member.

64. The method of claim 63, wherein the separating member is a mechanical separating element.

30 65. The method of claim 63, wherein the separating member is a gel.

66. A method for treating, comprising the steps of:

collecting a cell population that comprises hematopoietic stem cells, wherein the cell population is collected in a container comprising one or more caspase inhibitors; and administering at least a portion of the collected cell population into a
5 patient.

67. The method of claim 66, wherein umbilical cord blood or placental blood is collected into the container.

68. The method of claim 66, wherein at least a portion of the one or more caspase inhibitors are administered into the patient along with the at least a portion of
10 the collected cell population.

69. The method of claim 66, further comprising the step of cryopreserving the collected cell population, and thawing the collected cell population, prior to the step of administering.

70. The method of claim 66, wherein the container comprises at least two
15 caspase inhibitors.

71. The method of claim 69, wherein at least a portion of a cryopreservative used in the cryopreserving step is administered into the patient along with the at least a portion of the one or more caspase inhibitors and the at least a portion of the collected cell population.

20 72. A method for treating, comprising the steps of:

performing a leukapheresis process to collect a cell population that comprises hematopoietic stem cells, wherein the cell population is collected in a container comprising one or more caspase inhibitors; and

administering at least a portion of the collected cell population into a
25 patient.

73. The method of claim 72, wherein at least a portion of the one or more caspase inhibitors are administered into the patient along with the at least a portion of the collected cell population.

74. The method of claim 72, further comprising the step of cryopreserving
30 the collected cell population, and thawing the collected cell population, prior to the step of administering.

75. The method of claim 72, wherein the container comprises at least two caspase inhibitors.

76. The method of claim 74, wherein at least a portion of a cryopreservative using in the cryopreserving step is administered into the patient along with the at least a portion of the one or more caspase inhibitors and the at least a portion of the collected cell population.

7

5